



DEPARTMENT OF HEALTH & HUMAN SERVICES

95130d  
Public Health Service  
Food and Drug Administration  
Los Angeles District

19701 Fairchild  
Irvine, California 92612-2506  
Telephone (949) 608-2900

## WARNING LETTER

### **CERTIFIED MAIL** **RETURN RECEIPT REQUESTED**

**W/L 05-05**

December 21, 2004

In reply refer to Warning Letter LOS-05-05

Ms. Beryl Ann Byrd  
Just Fabulous Pastries, Inc.  
4564 Alvarado Canyon Road, Suite A  
San Diego, CA 92120-4311

Dear Ms. Byrd:

The Food and Drug Administration conducted an inspection of your firm located at 4564 Alvarado Canyon Road, Suite A, San Diego, CA, on September 30 – October 1, 2004. The inspection found that you did not follow food Good Manufacturing Practice (GMP) regulations, Title 21, Code of Federal Regulations (21 CFR) Part 110. At the conclusion of the inspection, you were issued a Form FDA-483 (copy enclosed), which delineated a number of gross insanitary conditions present in your facility at the time of that inspection. We have determined that these conditions cause the products manufactured in your facility to be adulterated within the meaning of Section 402(a)(4) (copy attached) of the Food, Drug, and Cosmetic Act (the Act), in that they were prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You can also find links to the Act on FDA's website at [www.fda.gov](http://www.fda.gov).

The following is a list of the insanitary conditions observed by our investigator during the inspection:

1. Employees did not wash and sanitize their hands thoroughly in an adequate hand-washing facility after each absence from the work station and any time their hands may have become soiled or contaminated. Specifically, employees were observed leaving their work stations, entering the cooler and touching the cooler door handle, lifting buckets of bulk ingredients, touching the bottom of scales, and handling other

unsanitary surfaces. Those employees then returned to processing food without first washing and sanitizing their hands. Some of the food processing involved direct bare-hand contact with ready-to-eat foods. [21 CFR 110.10 (b)(3)]

2. Hand-washing and hand-sanitizing facilities were not provided at each location in the plant where needed. Specifically, there is no hand-washing sink located in the production room. The only sink in the production room is a two-compartment dish washing sink. The sink is used during production for washing equipment and utensils. In addition, there was no hand sanitizer available for employees that directly manipulate ready-to-eat food by hand. [21 CFR 110.37 (e)(1)]
3. The facility and procedure used for cleaning and sanitizing equipment and utensils has not been shown to provide adequate cleaning and sanitizing treatment. Specifically, an employee was observed washing utensils, baking pans, and other food production equipment, which items were not sanitized after cleaning. [21 CFR 110.35 (a)]
4. Food was not stored under conditions and controls necessary to minimize the potential for growth of microorganisms and contamination. Specifically, food items in the freezer were stored directly below a leaking condensing unit, and leakage from that unit was observed on the outer wrapper of some of those items. A cart holding unwrapped cakes was stored directly below a leaking condensing unit in the cooler. Leakage from that unit was observed on the top sheet pan of the cart. [21 CFR 110.80 (b)(2)]
5. Employees were observed drinking beverages in areas where food is exposed and equipment or utensils are washed. Specifically, employees were observed drinking coffee and water at their food production work stations. [21 CFR 110.10 (b)(8)]
6. Employees failed to remove unsecured jewelry or other objects which might fall into food, equipment, and containers. Specifically, two female employees were observed wearing jewelry while manufacturing desserts. One employee was wearing earrings and a lip ring. The other employee was wearing earrings. [21 CFR 110.10 (b)(4)]
7. Employees failed to wear hair nets and appropriate hair restraints where appropriate. Specifically, the owner of the facility was manufacturing desserts without any hair restraint. [21 CFR 110.10 (b)(6)]
8. Toxic cleaning compounds were not properly identified in a manner that protects against contamination of food, food-contact surfaces, and food-packaging materials. Specifically, an unidentified spray bottle containing cleaning chemicals was observed on a cart near the dish washing area. [21 CFR 110.35 (b)(2)]
9. Toilet facilities lack self-closing doors. Specifically, the employee restroom located adjacent to the production area lacks a self-closing door. [21 CFR 110.37 (d)(3)]

Ms. Beryl Ann Byrd, Just Fabulous Pastries, Inc.

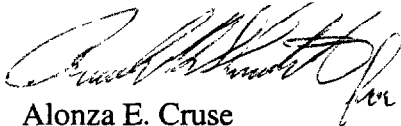
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The above violations are not meant to be an all-inclusive list of deficiencies in your facility. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with the Act and applicable regulations. You should take prompt action to correct the violations observed during FDA's most recent inspection. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

Please respond in writing within fifteen (15) days from your receipt of this letter. Your response should include each step that has been taken to completely correct the current violations and to prevent the recurrence of similar violations, the time within which correction will be completed, and any documentation necessary to show that correction has been achieved. If you cannot complete all necessary corrections before you respond, please explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: MaryLynn Datoc, Compliance Officer, 19701 Fairchild, Irvine, California, 92612. If you have any questions regarding any issue in this letter, please contact MaryLynn Datoc, Compliance Officer, at telephone number 949-608-4428.

Sincerely,

A handwritten signature in black ink, appearing to read 'Alonza E. Cruse', with a stylized flourish at the end.

Alonza E. Cruse  
District Director

Enclosures: 21 CFR Part 110  
Section 402(a)(4) of the FD&C Act